

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Applicant: Cooker) Group Art Unit: 1615
S/N.: 09/614,243) Examiner: Robert M. Joynes
Filed: 7/12/00)
For: Oral Delivery System And) Docket No. COO 10100
Method For Making Same

DECLARATION OF JOHN COOKER UNDER RULE 132

Box AF
Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

John Cooker does hereby declare under penalty of perjury that:

1. I am the inventor of the invention claimed in the above-referenced patent application.
2. The statements below are based on the amendments to the claims being submitted herewith.
3. I have reviewed Wong U.S. Patent No. 5,198,229. The Wong device is made up of chambers. At least one of these chambers is a buoyancy chamber. Due to the buoyancy chamber, the Wong device, in its first stage, floats on stomach liquids. The Wong device achieves density

by release of air in the outer chamber, not by the addition of a filler. Therefore, the Wong device certainly cannot facilitate swallowing if it is configured to float first on liquids. On the other hand, the oral dosage form, as recited in amended claim 1 of the instant application, completely sinks in the liquid with which the oral dosage is taken. Therefore, the buoyancy chamber of the Wong device would defeat the entire purpose of invention as claimed in amended claim 1. Therefore, it is my opinion that Wong does not anticipate, teach or suggest the claimed invention.

4. I have reviewed Eckenhoff U.S. Patent No. 5,098,425. The principle object of the Eckenhoff invention is to "provide both a novel and useful therapeutic dispensing device for use in animal therapy" (see column 1, lines 67-68-column 2, line 1). The Eckenhoff invention is directed to a time released dispenser. The therapeutic dispensing device of Eckenhoff uses metal as densifying agents. These metals must be passed out of the animal's body (see column 10, lines 1-39). The use of metals as densifying agents is certainly not an acceptable option for oral dosages to be ingested by humans. As explained throughout the instant specification, the oral dosage form of my invention utilizes fillers common to the pharmaceutical industry which can be digested by humans. In view of these differences between the Eckenhoff invention and my oral dosage form, as now claimed, it is my opinion that Eckenhoff does not anticipate, teach or suggest the oral dosage form as now claimed in amended claim 1.

5. I have reviewed Hampton U.S. Patent No. 5,089,270. One of the main objects of the Hampton invention is to provide a solid medicament with the appearance of a gelatin capsule. Amended claim 1 of the instant application now recites the oral dosage form as being a capsule having a filler disposed in one portion of the capsule to create a weighted or high-density end of the capsule that will cause the entire capsule to sink in the liquid with which the capsule is taken.

Therefore, it is my opinion that Hampton does not anticipate, teach or suggest the oral dosage form recited in amended claim 1.

6. All statements made herein of my own knowledge are true and all statements made on information or belief are believed to be true, and these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code and such willful false statements may jeopardize the validity of the instant patent application and any patent arising therefrom.

Respectfully submitted,

Date.

June 22, 2002

John Cooker

John Cooker